IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors:	Törmälä et al.
Serial No.:	08/921,533
Filing Date:	September 2, 1997
For:	BIOACTIVE AND BIODEGRADABLE COMPOSITES OF POLYMERS AND CERAMICS OR GLASSES AND METHOD TO MANUFACTURE SUCH COMPOSITES
Examiner:	Lakshmi S. Channavajjala
Art Unit:	1615

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APPEAL BRIEF UNDER 37 C.F.R. 41.37

SIR:

This brief is in furtherance of the Notice of Appeal filed on August 21, 2006. An appeal brief was originally filed in this application on September 8, 2005. In response, the Examiner re-opened prosecution to cite new art against the pending claims. Appellants have chosen to renew their appeal pursuant to MPEP 1204.01. The appeal brief fee was already paid on September 8, 2005, so Applicants believe no further fee is due in this respect. However, if any further fee is due, the Office is authorized to charge Kenyon & Kenyon's Deposit Account No. 11-0600 for such fees.

I. REAL PARTY IN INTEREST

Linvatec Biomaterials Oy is the real party in interest for all issues related to this appeal by virtue of the assignment from the inventors to Bionx Implants Oy recorded on February 23, 1998 at Reel 9007 and Frame 0360 and by virtue of the name change of

Bionx Implants Oy to Linvatec Biomaterials Oy recorded on January 5, 2006 at Reel 016971 and Frame 0576.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals, interferences, or judicial proceedings known to Appellants, Appellants' legal representative, or assignee which may be related to, directly affect, or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-6 and 9-22 are pending in the present application. Claims 7 was cancelled by the amendment of August 25, 2003 and claim 8 was cancelled by the amendment of October 25, 2004. The attached claims reflect the status of the claims as of the Final Office Action of March 8, 2005.

IV. STATUS OF AMENDMENTS

No amendments were made in the Response under 37 C.F.R. 1.116 of April 5, 2005.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to a biodegradable and bioactive composite material comprising two different reinforcing phases and one matrix phase. One reinforcing phase is a resorbable polymeric reinforcing component and the other reinforcing phase is a ceramic reinforcing component mixed with the matrix component (phase). (See page 5, lines 17-19 and Figure 1).

The resorbable polymeric reinforcing component can be a fibrillated biodegradable or bioerodible polymer and the diameter of the reinforcing fibers can vary from between 4 microns and 800 microns, and preferably between 20 microns and 500 microns. The polymeric reinforcing component can be used as plain fiber or in modified form such as braided or woven into two or three dimensional structures. (See page 7, lines 10-11). Table 1 of the specification provides a list of resorbable polymers that can be used for the resorbable polymeric reinforcing component. (See pages 14-15).

The ceramic reinforcing component can comprise of bioceramic or bioglass, or a mixture of these and acts as a bioactive, bony ongrowth agent that provides a reservoir of calcium and phosphate ions, thus accelerating the healing time for bony fractures. While the matrix polymer degrades, bone can attach to the residual ceramic or glass particles. (See page 6, lines 9-11). The ceramic reinforcing component has a particle size of between 60 microns and 150 microns. (See page 6, line 7). As described by the specification:

> The defined particle size of the ceramic element in the composite described in this invention is relatively big compared to conventionally used particle sizes for fillers or granules. In this invention, it was found unexpectedly that composites having bigger particle size ceramic elements are more biocompatible and cause less irritation to tissue than composites utilizing a ceramic element having small particle size. Biocompatibility is easily seen in histological studies. In tissue near and inside the degrading composite implants having small ceramic particles[,] there exists more giant cells than around and inside the degrading composite implants containing big (coarser) ceramic particles.

Page 6, lines 14-22.

This biocompatibility is also reported in Example 11 where two sets of sample plates of a composite material with a polymeric matrix component, a resorbable polymeric reinforcing component and a bioglass or bioceramic component (hydroxyapatite) were compared. The mean particle diameter of hydroxyapatite powder in the first set of plates was 7.43 microns and in the second set of plates was 80 ±20 microns. (See page 13, lines 9-16). Histology studies of ten animals showed that in and around the composite plates from the first set, there existed significantly more giant cells than in the tissue of animals implanted with the composite plates from the second set. See page 13, lines 18-22. Thus, the hydroxyapatite particles of 80 ±20 microns were shown to be more biocompatible. (See page 13, lines 22-23).

The amount of the ceramic reinforcing component can be 0.15 to 0.9 volume fraction and preferably between 0.2 and 0.6 volume fraction. Table 2 of the specification provides a list of bioceramics and bioglasses that can be used for the ceramic reinforcing component. (See page 15 to 16). The bioceramics or bioglasses can be in the form of a powder, flake, sphere, fiber, or other forms. (See page 6, line 6).

The composite material can contain various additives and modifiers which improve the processability of the composite. (See page 6, lines 23-24). Such additives include surface modifiers to improve the attachment between the polymeric and ceramic components. (See page 6, line 23 to page 7, line 1). The composite can also contain

pharmaceutically active agents such as antibiotics, chemotherapeutic agents, wound-healing agents, growth hormones, and anti-coagulants. Such agents are used to enhance the bioactive features of the composite and improve the healing process of the tissue. (See page 7, lines 2-5).

The composite materials of the present invention have improved mechanical properties compared to non-reinforced devices because the reinforcement changes the behavior of the material from brittle to ductile and makes the device more reliable under load. (See page 4, lines 20-23).

The present invention also provides a method of manufacturing a composite material as described above. The polymer matrix component and the ceramic reinforcing component can be mixed together by powder mixing, melt mixing, or solvent mixing. (See page 7, lines 7-9). The mixture of the polymeric matrix component and the ceramic reinforcing component can be combined with the polymeric reinforcing component by melt mixing, by coating, or by using solvent as an intermediate to preform the material. (See page 7, lines 11-13). The material can be produced in its final form by various techniques including compression molding, filament winding, mechanical machining, or injection molding to any desired shape. (See page 7, lines 14-16).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

In the Office Action of April 19, 2006, the Examiner re-opened prosecution of this previously appealed case. The rejection of April 19, 2006 rejected claims 1-6 and 9-22 as being rendered obvious under the judicially created doctrine of obviousness-type double patenting by claims 1-10 of U.S. Patent No. 6,406,498 to Tormala ("the '498 patent") in view of U.S. Patent No. 4,743,257 to Tormala ("the '257 patent") and U.S. Patent No. 4,778,471 to Bajpai ("the '471 patent").

The Examiner has not clearly identified which claims are rejected in view of which reference. The Examiner simply providing a running description of the references without citing any specific teachings of the art against any specific claims. Appellants will therefore address each reference with respect to each claim.

VII. ARGUMENT

Claim 1

Claim 1 recites a bioceramic or bioglass reinforcing component having " a particle size between 60 um and 150 um." As previously stated, claims 1-10 of the '498 patent recite glass or ceramic particles dispersed in a polymer matrix but do not recite any size of the particles, let alone a size between 60 microns and 150 microns. Further, the '257 patent does not make up for this deficiency as the '257 patent does not describe any bioglass or bioceramic particles, let alone any size of such particles, let alone the particle size range as recited in claim 1.

With respect to the '471 patent, Appellants submit that a *prima facie* case of obviousness has not been established since there is no motivation to combine the '471 patent with the claims of the '498 patent. The claims of the '498 patent are clearly directed to a surgical composite material that comprises a polymer matrix that has bioactive glass or ceramic dispersed therein. The '471 patent, on the other hand, is directed to a ceramic used as a drug delivery system, cement or grout or a preformed implant or ceramic block. (See col. 3, lines 10-16). There is no suggestion that the powdered ceramic described in the '471 patent should be dispersed in any way in other material to form a composite material. In fact, most of the disclosure of the '471 patent is directed towards the powdered ceramic being mixed with a setting agent to provide a surgical cement or grout. Although the '471 patent states that the ceramic can be used as a bone implant device, upon a closer reading of the '471 patent, it is apparent that such a statement refers to the powdered ceramic being used to form a surgical cement that serves as a preform implant or ceramic block to repair bone. (See col. 4, lines 15-23). There is no teaching or suggestion that the particles should serve another purpose, such as being dispersed in a polymer matrix, as recited by the claims of the '498 patent. For at least this reason, Appellants submit that there is no motivation to combine the '471 patent with the claims of the '498 patent.

Furthermore, as Appellants have stated before, the range of particle size recited in claim 1 is critical. Specifically, as Appellants pointed out in the October 25, 2004 Response to Office Action, the August 25, 2003 Response to Office Action and the June 28, 2004 Response to Office Action, this claimed range achieves unexpected results relative to the prior art. The specification states at page 6, line 7 that the particle size is

preferably between 60 μm and 150 μm. The specification further states on page 6, lines 14-22:

> [t]he defined particle size of the ceramic element in the composite described in this invention is relatively big compared to conventionally used particle sizes for fillers or granules. In this invention, it was found unexpectedly that composites having bigger particle size ceramic elements are more biocompatible and cause less irritation to tissue than composites utilizing a ceramic element having small particle size. Biocompatibility is easily seen in histological studies. In tissue near and inside the degrading composite implants having small ceramic particles there exists more giant cells than around and inside the degrading composite implants containing big (coarser) ceramic particles.

The increased biocompatibility seen with coarser particles is supported by Example 11 of the present specification which compares histological studies of composite plates in ten animals with finer hydroxyapatite powder (7.43 microns) and coarser hydroxyapatite particles (80 +/- 20 microns). As shown in Example 11:

> in histological studies it was clearly seen, that in and around the composite plates with finer hydroxyapatite powder [7.43 microns] there existed significantly more giant cells than in the tissue of reference animals containing composite plates with coarser hydroxyapatite particles [80 +/- 20 microns]. Thus, coarser hydroxyapatite particles were shown to be more biocompatible.

Page 13, lines 18-23.

Appellants have therefore shown that the claimed particle size of 60 μm to 150 μm of the bioglass or bioceramic reinforcing component is contrary to conventional practice and renders unexpected benefits, such as greater biocompatibility and less irritation to tissue compared to particle sizes taught in the art. Specifically, Example 11 describes hydroxyapatite particles between 60 microns and 100 microns (i.e. 80 +/- 20 microns) compared to hydroxyapatite particles within the range used in the prior art (*i.e.* hydroxybutyrate powder compounded with particular hydroxyapatite powder with a mean particle size of 8.6 microns as descirbed Doyle et al, "In vitro and in vivo evaluation of polyhydroxybutyrate and of polyhydroxybuytrate reinforced with hydroxyapatite," Biomaterials, vol. 12 (November 1991) at page 842).

This evidence has been presented in at least four previous responses to Office Actions (See August, 25, 2003 Response, June 28, 2004 Response, October 25, 2004

Response, and April, 5, 2005 Response) as well as the original appeal brief of September 8, 2005. The Examiner has yet to properly address this evidence in the Office Actions and explain why this evidence is unconvincing.

Claim 2, 17, 18, 19, and 20

Claims 2, 17, 18, 19, and 20, which are directed to methods of manufacturing a biodegradable composite material according to claim 1, are not rendered obvious by the combination of the '498 claims and the '257 patent because such combination does not describe each and every element of the claims. The '498 patent recites no method of manufacturing a biodegradable composite. The '257 patent makes no mention of a bioceramic or bioglass reinforcing component. Therefore, steps (c) and (f) of claim 2 are not disclosed by the combination of the '257 patent and the '498 claims. To the extent that the Examiner is citing the '471 patent for describing glass of ceramic particles, the combination of all these references still do not describe at least steps (c) and (f) of claim 2 since there is no description in any of these references alone or collectively of mixing a polymer and a bioglass or bioceramic component to form a mixture and then combining this mixture with a second polymer in fiber form to form a second mixture. The Examiner has provided no basis for finding that these steps are disclosed by these references and does not even discuss these steps in the Office Action. The Examiner also does not address the subject matter of the further dependent claims 17, 18, 19 and 20 and what sections of the references allegedly describe this additional subject matter. Therefore, it is unclear what the basis for the §103 rejection is for these claims. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claims 2, 17, 18, 19 and 20 are not rendered obvious by claims 1-10 of the '498 patent.

Claim 3

Claim 3 recites that the resorbable polymeric reinforcing component is in fiber form with a fiber diameter being greater than the diameter or particle size of the bioceramic or bioglass reinforcing component. None of claims 1-10 of the '498 patent recite a composite comprising both a resorbable polymeric reinforcing component in fiber form and a bioceramic or bioglass reinforcing component (as recited by claim 3, by virtue of its dependency to claim 1), let alone a composite where the polymeric

reinforcing component has a fiber diameter greater than the diameter or particle size of the bioceramic or bioglass reinforcing component. Claim 8 simply recites "bioabsorbable or bioactive fibers." To the extent that this is read to encompass the claimed resorbable polymeric reinforcing component in fiber form, this claim still does not recite a bioceramic or bioglass reinforcing component, as recited by claim 3. To the extent that this claim is read to encompass the claimed bioceramic or bioglass reinforcing component, this claim still does not recite a resorbable polymeric reinforcing component in fiber form, as recited by claim 3. Furthermore, these deficiencies are not cured by the '471 patent or the '257 patent. In neither the Office Action of March 8, 2005 nor the Office Action of April 19, 2006 has the Examiner provided a basis for which claim 3 is rendered obvious by claims 1-10 of the '498 patent in view of the '471 patent and/or the '257 patent. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claim 3 is not rendered obvious by claims 1-10 of the '498 patent in view of the '257 patent and/or the '471 patent.

Claim 4

Claim 4 recites that the resorbable polymeric reinforcing component is in fiber form with a fiber diameter being greater than the diameter or particle size of the bioceramic or bioglass reinforcing component and wherein at least one fiber has variable thickness. None of claims 1-10 of the '498 patent teach a composite comprising both a resorbable polymeric reinforcing component in fiber form and a bioceramic or bioglass reinforcing component (as recited by claim 4, by virtue of its dependency to claim 1), let alone a composite where the polymeric reinforcing component has a fiber diameter greater than the diameter or particle size of the bioceramic or bioglass reinforcing component and wherein at least one of the fibers has a variable thickness. Claim 8 simply recites "bioabsorbable or bioactive fibers." To the extent that this is read to encompass the claimed resorbable polymeric reinforcing component in fiber form, this claim still does not recite a bioceramic or bioglass reinforcing component, as recited by claim 4. To the extent that this claim is read to encompass the claimed bioceramic or bioglass reinforcing component, this claim still does not recite a resorbable polymeric reinforcing component in fiber form, as recited by claim 4. Furthermore, these deficiencies are not cured by the '471 patent or the '257 patent. The Examiner has provided no basis for which claim 4 is rendered obvious by claims 1-10 of the '498 patent

in view of the '471 patent and/or the '257 patent. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claim 4 is not rendered obvious by claims 1-10 of the '498 patent in view of the '257 patent and/or the '471 patent.

Claims 5 and 6

Claims 5 and 6, depend either directly or indirectly from claim 1 and therefore contain all of the limitations of claim 1. For the reasons stated above with respect to claim 1, Appellants submit that claims 5 and 6 are not rendered obvious by the '498 patent in view of the '471 patent or the '257 patent.

Claims 9 and 10

Claims 9 and 10 recite that the amount of the bioceramic or bioglass reinforcing component is 0.15 to 0.9 and 0.2 to 0.6 volume fraction, respectively. Claims 1-10 of the '498 patent do not recite either of these amounts. In the Office Action of April 19, 2006, the Examiner states that "absent unexpected results, '471 recognizes various ceramic materials (col. 2) and their particle sizes that are suitable for implant as well as drug delivery purposes and accordingly optimizing the volume of ceramic particles in the implant or composite material of '498 would have been within the scope of a skilled artisan." The '498 patent claims are completely silent as to any amount and therefore, contrary to the Examiner's assertion, there is no amount range to optimize based on the '498 patent's claims. The '498 patent claims simply provide no guidance to any particular amount range for the claimed bioabsorbable or bioactive particles. Moreover, the Examiner has pointed to no teaching that indicates that the amount of the bioglass or bioceramic reinforcing component is a result-effective variable. Regarding the Examiner's statement above about the '471 patent, such a description is only with respect to particle size not particle volume. As such, there is no recognition in the '471 patent (or the '257 patent for that matter) that the volume fraction of the bioceramic or bioglass reinforcing component has any effect on the matrix. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claims 9-10 are not rendered obvious by claims 1-10 of the '498 patent in view of the '471 patent and/or the '257 patent.

Claims 11, 12 and 13

Claims 11, 12 and 13, depend either directly or indirectly from claim 1 and therefore contain all of the limitations of claim 1. For the reasons stated above with respect to claim 1, Appellants submit that claims 11, 12 and 13 are not rendered obvious by the '498 patent in view of the '471 patent and/or the '257 patent.

Claim 14

Claim 14 recites that the bioceramic or bioglass reinforcing component is selected from a specific group. Claims 1-10 of the '498 patent in no way describe any specific types of bioactive glass or ceramic particles, let alone the specific types of particles recited by claim 14. Neither the '471 patent nor the '257 patent make up for this deficiency. The Examiner has provided no basis for which claim 14 is rendered obvious by claims 1-10 of the '498 patent in view of the '471 patent and/or the '257 patent. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claim 14 is not rendered obvious by claims 1-10 of the '498 patent in view of the '471 patent and/or the '257 patent.

Claim 15

Claim 15 recites that the composite material exhibits ductile behavior under load. Claims 1-10 of the '498 patent in no way describe this limitation. Neither the '471 patent nor the '257 patent make up for this deficiency. The Examiner has provided no basis for which claim 15 is rendered obvious by claims 1-10 of the '498 patent in view of the '471 patent and/or the '257 patent. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claim 15 is not rendered obvious by claims 1-10 of the '498 patent in view of the '257 patent and/or the '471 patent.

Claim 16

Claim 16 recites a composite material comprising a bioceramic or bioglass reinforcing component and a resorbable polymeric reinforcing component in fiber form having a diameter greater than the diameter or particle size of the bioceramic or bioglass reinforcing component. None of claims 1-10 of the '498 patent teach a composite comprising both a resorbable polymeric reinforcing component in fiber form and a

bioceramic or bioglass reinforcing component, let alone a composite where the polymeric reinforcing component has a diameter greater than the diameter or particle size of the bioceramic or bioglass reinforcing component. Claim 8 simply recites "bioabsorbable or bioactive fibers." To the extent that this is read to encompass the claimed resorbable polymeric reinforcing component in fiber form, this claim still does not recite a bioceramic or bioglass reinforcing component, as recited by claim 16. To the extent that this claim is read to encompass the claimed bioceramic or bioglass reinforcing component, this claim still does not recite a resorbable polymeric reinforcing component in fiber form, as recited by claim 16. Neither the '471 patent nor the '257 patent make up for this deficiency. The Examiner has provided no basis for which claim 16 is rendered obvious by claims 1-10 of the '498 patent in view of the '471 patent and/or the '257 patent. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claim 16 is not rendered obvious by claims 1-10 of the '498 patent in view of the '257 patent and/or the '471 patent

Claims 21 and 22

Claims 21 and 22 recite that the resorbable polymeric reinforcing component is in fiber form with a fiber diameter between 4 and 800 microns and 200 and 500 microns, respectively. None of claims 1-10 of the '498 patent teach a composite comprising both a resorbable polymeric reinforcing component in fiber form and a bioceramic or bioglass reinforcing component (as recited by claims 21 and 22, by virtue of their dependency to claim 1) or any particular fiber diameter, let alone the specific fiber diameter recited by claims 21 and 22. Claim 8 simply recites "bioabsorbable or bioactive fibers." To the extent that this is read to encompass the claimed resorbable polymeric reinforcing component in fiber form, this claim still does not recite a bioceramic or bioglass reinforcing component, as recited by claims 21 and 22. To the extent that this claim is read to encompass the claimed bioceramic or bioglass reinforcing component, this claim still does not recite a resorbable polymeric reinforcing component in fiber form, as recited by claims 21 and 22. Neither the '471 patent nor the '257 patent make up for this deficiency. The Examiner has provided no basis for which claims 21 and 22 is rendered obvious by claims 1-10 of the '498 patent in view of the '471 patent and/or the '257 patent. For at least this reason and the reasons stated above with respect to claim 1,

Appellants submit that claims 21 and 22 are not rendered obvious by claims 1-10 of the '498 patent in view of the '257 patent and/or the '471 patent.

APPENDICES

VIII. CLAIMS APPENDIX

The claims in their current form are presented below:

Claim 1. A biodegradable and bioactive composite material for surgical osteosynthesis applications comprising: i) at least one resorbable polymeric matrix component, ii) at least one resorbable polymeric reinforcing component and iii) at least one bioceramic or bioglass reinforcing component mixed with said matrix component, wherein the bioceramic or bioglass reinforcing component has a particle size of is between 60 μm and 150μm.

Claim 2. A method of manufacturing a biodegradable composite according to claim 1, comprising the steps of:

a) selecting at least one first polymer for the matrix;

b) selecting at least one bioceramic material, bioglass material or mixture thereof for use as the bioceramic or bioglass reinforcing component;

c) mixing said first polymer and said bioceramic or bioglass reinforcing component together to form a mixture;

d) selecting at least one second polymer in a fiber form for the resorbable polymeric reinforcing component;

e) placing said second polymer into a desired formation;

f) combining said mixture of step (c) and said formation of step (e) to yield a second mixture; and

g) subjecting the second mixture of step (f) to heat or pressure.

3. The composite material according to claim 1 wherein the at least one resorbable polymeric reinforcing component is in fiber form, with fiber diameter being greater than the diameter or particle size of the bioceramic or bioglass reinforcing component.

4. The composite material according to claim 3 wherein the at least one resorbable polymeric reinforcing component comprises at least one fiber having a variable thickness.

5. The composite material according to claim 1 wherein the at least one resorbable polymeric reinforcing component is selected from the group consisting of a fabric, a plain polymeric fiber structure, a woven structure and a braided structure.

6. The composite material according to claim 1 wherein the form of the bioceramic or bioglass reinforcing component is selected from the group consisting of powder, flakes, spheres and fibers.

7. (Cancelled)

8. (Cancelled)

9. The composite material according to claim 1 wherein the amount of bioceramic or bioglass reinforcing component is 0.15 to 0.9 volume fraction.

10. The composite material according to claim 9 wherein the amount of bioceramic or bioglass reinforcing component is 0.2 to 0.6 volume fraction.

11. The composite material according to claim 1 further comprising additives selected from the group consisting of surface modifiers to improve attachment between the resorbable polymeric reinforcing component and the bioceramic or bioglass reinforcing component, a pharmaceutically active agent, and combinations thereof.

12. The composite material according to claim 11 wherein the pharmaceutically active agent is selected from the group consisting of antibiotics, wound-healing agents, chemotherapeutic agents, growth hormones, anticoagulants, and combinations thereof.

13. The composite material according to claim 1 wherein the resorbable polymeric matrix component is selected from the group consisting of polyglycolide, copolymers of glycolide, glycolide/L-lactide copolymers, glycolide/trimethylene carbonate copolymers,

polylactides, stereocopolymers of polylactides, poly-L-lactide, poly-DL-lactide, L-lactide/DL-lactide copolymers, copolymers of polylactides, lactide/tetramethylglycolide copolymers, lactide/trimethylene carbonate copolymers, lactide/d-valerolactone copolymers, lactide/e-caprolactone copolymers, polylactide/polyethylene oxide copolymers, polydepsipeptides, unsymmetrically 3,6-substituted poly-1,4-dioxane-2,5-diones, poly-b-hydroxybutyrate, poly-b-hydroxybutyrate/b-hydroxyvalerate copolymers, poly-b-hydroxypropionate, poly-p-dioxanone, poly-d-valerolactone, poly-e-caprolactone, methylmethacrylate-N-vinyl pyrrolidone copolymers, polyesteramides, polyesters of oxalic acid, polydihydropyrans, polyalkyl-2-cyanocrylates, polyurethanes, polyvinylalcohol, polypeptides, poly-b-malic acid, poly-b-alkanoic acids, polycarbonates, polyorthoesters and polyphosphates.

14. The composite material according to claim 1 wherein the bioceramic or bioglass reinforcing component is selected from the group consisting of hydroxyapatite, calcium phosphates, alumina, zirconia, bioactive gel-glass, alpha wollastonite glass ceramic, and mixtures of bioglass and bioceramic materials.

15. The composite material according to claim 1 wherein the composite material exhibits ductile behavior under load.

16. A biodegradable and bioactive composite material for surgical osteosynthesis applications comprising: i) at least one resorbable polymeric matrix component, ii) at least one resorbable polymeric reinforcing component in fiber form, and iii) at least one bioceramic or bioglass reinforcing component mixed with said matrix component, the diameter of the resorbable polymeric reinforcing component being greater than the diameter or particle size of the bioceramic or bioglass reinforcing component, wherein the bioceramic or bioglass reinforcing component has a particle size between 60 μm and 150μm.

17. The method according to claim 2 wherein the mixing of step c) is accomplished by melt mixing.

18. The method according to claim 2 wherein the mixing of step c) is accomplished by solvent mixing.

19. The method according to claim 2 wherein step e) is accomplished manually.

20. The method according to claim 2 wherein step e) is accomplished with use of a machine.

21. The composite material according to claim 1 wherein the at least one resorbable polymeric reinforcing component is in fiber form with a fiber diameter between 4μm and 800μm.

22. The composite material according to claim 21 wherein the fiber diameter is between 20μm and 500μm.

IX. EVIDENCE APPENDIX

No evidence is being submitted with this Appeal Brief.

X. RELATED PROCEEDINGS APPENDIX

Per section (II), there are no other appeals, interferences, or judicial proceedings known to Appellants, appellant's legal representative, or assignee which may be related to, directly affect, or be directly affected by or have a bearing on the Board's decision in the pending appeal.

XI. CONCLUSION

Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the Examiner's decision rejecting claims 1-6 and 9-22 and direct the Examiner to pass the case to issue.

Respectfully submitted,

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